DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-529/S-033

Ross Products Division
Abbott Laboratories
Attention: Robert J. Matis
Manager, Drug Regulatory Affairs
625 Cleveland Avenue
Columbus, OH 43215-1724

Dear Mr. Matis:

Please refer to your supplemental new drug application dated April 9, 2003, received April 10, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pediazole® (erythromycin ethylsuccinate and sulfisoxazol acetyl for oral suspension), Oral Suspension.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application provides for:

1. Revised labeling to comply with the Final Rule titled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

2. Revised Geriatric Use subsection.

We completed our review of this supplemental new drug application and it is approved effective on the date of this letter, for use as recommended in the labeling (package insert) submitted on April 9, 2003.

The following changes should be incorporated in your next labeling supplement:

1. Revise the *Carcinogenesis, Mutagenesis, Impairment of Fertility* and *Pregnancy* subsection of the package insert by reporting the ratio of the dose (e.g., teratogenic effects expressed in mg/sq.m.).

2. Delete from the labeling, the second statement under *Mutagenesis* subsection that reads "Ames mutagenic assays have not been performed with sulfisoxazole."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth

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